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नेत्र रोग संबंधी रोपण — इंट्राऑक्यूलर लैंस

भाग 8 मौलिक अपेक्षाएँ

Indian Standard

OPHTHALMIC IMPLANTS — INTRAOCULAR LENSES

PART 8 FUNDAMENTAL REQUIREMENTS

ICS 11.040.70

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

June 2011 **Price Group 2**

Ophthalmic Instruments and Appliances Sectional Committee, MHD 05

NATIONAL FOREWORD

This Indian Standard (Part 8) which is identical with ISO 11979-8 : 2006 'Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard is published in ten parts. Other parts of this series are:

Part 1	Vocabulary
Part 2	Optical properties and test methods
Part 3	Mechanical properties and test methods
Part 4	Labelling and information
Part 5	Biocompatibility
Part 6	Shelf-life and transport stability
Part 7	Clinical investigations
Part 9	Multifocal intraocular lenses
Part 10	Phakic intraocular lenses

The IS/ISO 11979 series will supersede IS 14323 : 1996 'Intraocular lenses — Specification' and after the publication of this series of standards, IS 14323 shall be treated as withdrawn.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 11979-1 : 2006 Ophthalmic implants — Intraocular lenses — Part 1 : Vocabulary	IS/ISO 11979-1 : 2006 Ophthalmic implants — Intraocular lenses: Part 1 Vocabulary	Identical
ISO 11979-2 : 1999 Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods	IS/ISO 11979-2 : 1999 Ophthalmic implants — Intraocular lenses: Part 2 Optical properties and test methods	do

(*Continued on third cover*)

Indian Standard

OPHTHALMIC IMPLANTS — INTRAOCULAR LENSES

PART 8 FUNDAMENTAL REQUIREMENTS

1 Scope

This part of ISO 11979 specifies fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 10993-7:1995, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 11979-9, *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14630:2005, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

4 Safety and performance

The safety and performance of an intraocular lens shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis in accordance with ISO 14971.

In cases where a test method referenced in this part of ISO 11979 is not suitable for a certain design or a certain application, an alternative test method devised by the manufacturer shall be validated (see definition in ISO 9000), justified and documented.

5 Optical and mechanical properties

The manufacturer shall ensure that the intraocular lens conforms to applicable requirements in ISO 11979-2, ISO 11979-3, ISO 11979-9 and ISO 11979-10. The manufacturer shall record and justify any deviations from those standards.

6 Biocompatibility

The manufacturer shall have documented evidence that demonstrates the intraocular lens to be biocompatible by assessment in accordance with ISO 11979-5.

Manufacturers should take into consideration previous experience and data when determining the extent of further biocompatibility testing. See [1] for guidance on testing for biocompatibility.

7 Clinical evaluation

The first step in the clinical evaluation is a review of the available literature (published and unpublished) in order to determine if that information is sufficient to demonstrate the safety and performance of the intraocular lens (see Annex A of ISO 14155-1:2003). One option is to demonstrate that the new intraocular lens model is a minor modification of a model the safety and performance of which has previously been demonstrated.

NOTE Reference [2] provides a framework for assessment of whether or not a modification is minor for intraocular lenses for the correction of aphakia.

If the clinical evaluation identifies the need for a clinical investigation the requirements of ISO 14155-1 and ISO 14155-2 shall apply. In addition the following standards apply depending on the type of the intraocular lens:

a) for monofocal intraocular lenses for the correction of aphakia ISO 11979-7;

b) for multifocal intraocular lenses for the correction of aphakia ISO 11979-9;

c) for phakic monofocal intraocular lenses ISO 11979-10.

8 Manufacturing

Clause 8 of ISO 14630:2005 shall apply.

9 Sterilization

9.1 General

Clause 9 of ISO 14630:2005 shall apply with the following addition to 9.4 of that International Standard for intraocular lenses sterilized by ethylene oxide:

a) for the assay of the residue of ethylene oxide, an exhaustive solvent or head space extraction method shall be chosen;

b) the amount of residue of ethylene oxide shall conform with the requirements for intraocular lenses given in ISO 10993-7;

c) the residue of ethylene chlorohydrin shall not exceed a release of more than 2,0 μg per lens per day and not exceed 5,0 μg in total per lens.

For solvent extraction, a solvent affording exhaustive extraction should be chosen, e.g. one that adequately swells the lens material without disrupting the material itself. For headspace extraction, efficiency of extraction should be demonstrated by validation against an exhaustive solvent extraction method. In case the extraction is not exhaustive, release criteria should be lowered in proportion to the relative efficiency of the method. Supplementary guidance can be found in ISO 10993-7 and in Reference [3].

NOTE The level of ethylene glycol is correlated to the levels of ethylene oxide and ethylene chlorhydrin present. If the levels of ethylene oxide and ethylene chlorhydrin are within the limits set in b) and c), the level of ethylene glycol will be sufficiently low that there is no need to quantify it.

9.2 Bacterial endotoxins

The level of biological contamination shall be determined using a validated method for bacterial endotoxin testing in accordance with applicable pharmacopoeia [4][5][6].

The endotoxin level shall, on average, be 2,0 endotoxin units or less per lens. Lenses shall be extracted with endotoxin-free water, and test method and number of lenses per volume of water shall be chosen such that the test is sufficiently accurate to assure this level.

10 Packaging and shelf-life

The packaging shall meet the requirements of ISO 11979-6.

NOTE National and regional regulation can impose additional requirements.

11 Labelling and information

The intraocular lens as marketed shall be supplied with labelling and information in accordance with ISO 11979-4, ISO 11979-9 and ISO 11979-10 as applicable.

NOTE National and regional legislation can require additional labelling and information.

12 Documentation

All primary data, calculations, results, and reports shall be documented and kept on file by the manufacturer for as long as required by regulations.

Bibliography

[1] ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[2] ISO TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

[3] AAMI TIR No. 19:1998, *Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

[4] European Pharmacopoeia, Appendix XIV C. *Test for Bacterial Endotoxins*

[5] Japanese Pharmacopoeia, XIV 6. *Bacterial Endotoxins Test*

[6] United States Pharmacopoeia, <85> *Bacterial Endotoxins Test*

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International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 11979-3 : 2006 Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods	IS/ISO 11979-3 : 2006 Ophthalmic implants — Intraocular lenses: Part 3 Mechanical properties and test methods	Identical
ISO 11979-4 : 2008 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information	IS/ISO 11979-4 : 2008 Ophthalmic implants — Intraocular lenses: Part 4 Labelling and information	do
ISO 11979-5 : 2006 Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility	IS/ISO 11979-5 : 2006 Ophthalmic implants — Intraocular lenses: Part 5 Biocompatibility	do
ISO 11979-6 : 2007 Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability	IS/ISO 11979-6 : 2007 Ophthalmic implants — Intraocular lenses: Part 6 Shelf-life and transport stability	do
ISO 11979-7 : 2006 Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations	IS/ISO 11979-7 : 2006 Ophthalmic implants — Intraocular lenses: Part 7 Clinical investigations	do
ISO 11979-9 : 2006 Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses	IS/ISO 11979-9 : 2006 Ophthalmic implants — Intraocular lenses: Part 9 Multifocal intraocular lensesi	do
ISO 11979-10 : 2006 Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses	IS/ISO 11979-10 : 2006 Ophthalmic implants — Intraocular lenses: Part 10 Phakic intraocular lenses	do
ISO 10993-1 : 2003 Biological evaluation of medical devices — Part 1: Evaluation and testing	IS 12572 (Part 1) : 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (*first revision*)	Technically Equivalent

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 14155-1 : 2003	Clinical investigation of medical devices for human subjects — Part 1: General requirements
ISO 14155-2 : 2003	Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans
ISO 14630 : 2005	Non-active surgical implants — General requirements
ISO 14971 : 2007	Medical devices — Application of risk management to medical devices
ISO/TR 22979 : 2006	Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard alongwith amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

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